DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

June 30, 2000

WARNING LETTER
CHI-26-00

CERTIFIED MAIL
RETURN RECEIPT RESQUESTED

Mr. Mario Falco, President
Eastern Seafood Company, Inc.
1020 W. Hubbard
Chicago, IL 60622

Dear Mr. Falco:

On June 19 and 20, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant as a follow-up to our inspections on March 17-19, 1999, and August 5 and 6, 1998. The inspections covered the new FDA Hazard Analysis Critical Control Point (HACCP) regulations. Subsequent to the August 1998 inspection, we sent a letter dated September 3, 1998, notifying you of serious HACCP deficiencies observed during the inspection. Following the March 17-19, 1999 inspection, the investigator issued a FDA-483, Inspectional Observations, and Form FDA-3501 Domestic Seafood HACCP Report listing her observations that included continued serious deficiencies. This June 19-20, 2000 inspection was made again to evaluate HACCP requirements. At the conclusion of the inspection, you were issued a FDA-483 and 3501 describing deviations from FDA's Seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for Human Food (21 CFR 110). By virtue of these violations, the seafood products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigator found the following continued violations:

- Failure to prepare and implement a HACCP plan to control a food safety hazard that is reasonably likely to occur (Reference 21 CFR 123.6(b) and (c)). Examples include the lack of a HACCP plan to control scombrotoxin (histamine) formation in tuna and other scombroid fish handled at your facility.

- Failure to maintain monitoring record data as required by 21 CFR 123.6(c)(7) for critical control points in the processing of scombroid fish including but not limited to tuna.

The violations cited are not all inclusive since not every product could be evaluated at the time of the inspection. It is your responsibility to evaluate your program and ensure it is in compliance with the regulations. You should take prompt action to correct these violations. We are concerned that no substantial corrections have been made since the inspection in March 1999. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. We are also providing firms the opportunity to take a HACCP refresher course to assist in better understanding and working with the Seafood HACCP program. Please contact the local FDA office for further information. If you enroll in one of these courses, we will extend your response time or delay further regulatory action provided products are not critically compromised resulting in a danger to health.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention Paul A. Boehmer, Compliance Officer, at the Chicago District office.

Sincerely,

\s\
Raymond V. Mlecko
District Director